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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,431	01/03/2007	Gerhard Tivig	PHDE030358US	9506
38107 7590 03/27/2008 PHILIPS INTELLECTUAL PROPERTY & STANDARDS 595 MINER ROAD CLEVELAND, OH 44143			EXAMINER BITAR, NANCY	
			ART UNIT 2624	PAPER NUMBER
			MAIL DATE 03/27/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,431	Applicant(s) TIVIG ET AL.	
	Examiner NANCY BITAR	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/19/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 8-12 are objected to because of the following informalities: Claims 8-9 teaches a device as claimed in claim 6 but claim 6 teaches a method. Moreover claims 10-12 teaches a device as claimed in claim 5 whereas claim 5 teaches a method believes that claims 8-12 should depend on claim 7 that teaches a device. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 teaches a medical device comprising a device thus failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph. The claim is narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 16 teaches histogram data are measured below a selectable threshold level. There is nothing in the specification that teaches the threshold level as well as the histogram data being measured below the threshold level. Claim 17 teaches the histogram data is binned into selectably sized histogram bins. The closest explanation is in paragraph [0030] and figure 6 of the specification that teaches the bin is the width of an individual histogram column with respect to SpO2 value. It is not clear if the selectable size bin means the width of an individual bin that the user specifies or the SpO2 value of the histogram column. Appropriate correction is required.

Examiner Notes

Examiner cites particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that, in preparing responses, the applicant fully consider the references in

entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 6-9, 11-13, 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Seely et al (US 2003/0117296).

As to claim 1, Seely et al teaches a method of automatically displaying medical measurement data in which a computer receives(107, figure 1) the medical measurement data, automatically converts in real time(paragraph [0075]) the received measurement data into data for histograms(paragraph [0085]) and outputs the converted data as picture signals (paragraph [0088-0089]).

As to claim 2, Seely et al teaches a method as claimed in claim 1, wherein the measurement data are converted into dynamically updated real-time histogram readout objects (These values can be displayed as pairs of dynamic variability parameter histograms 526, 546, figure 5).

As to claim 3, Seely et al teaches a method as claimed in claim 1, wherein the histogram is filled with measurement data from a time window advancing in real time with selectable fixed length (see figure 6, note that for each patient parameter v.sub.k, a user, typically an attending physician, may select the number of data points m.sub.k to collect in order to perform the variability analysis).

As to claim 4, Seely et al teaches a method as claimed in claim 2, wherein, during the conversion, the computer generates aids for the retrospective analysis of histograms in the form of selectable functions that can be displayed on a viewing screen and outputs them together with the converted data combined as picture signals (note that the process 110 may be selected by a user from among a plurality of variability analysis options using a user interface 117, see paragraph [0061]).

As to claim 6, Seely et al teaches a method as claimed in claim 1, wherein the computer processes control signals that are produced by input means communicating with the computer and that serve to control the conversion and/or the output of the picture signals ,(The known individual patient interface and display 106a communicates measured values of the patient parameters to an apparatus in accordance with the invention that includes a processor 107 that performs individual patient data collection 108, paragraph [0061]) .

The limitation of claim 7 has been addressed above in claim 1.

Note that examiner examined claimed 8-12 to depend on the device of claim 7.

As to claim 8, Seely et al teaches a device, wherein the computer is designed to convert the measurement data to dynamically updated real-time histogram readout objects (Data update

preferably occurs as frequently as possible, preferably occurring each cycle. A cycle is defined as the time required performing the variability analysis for an individual patient parameter, paragraph [0075]).

As to claim 9, Seely et al teaches a device, wherein the computer is designed to generate, during the conversion, aids for the retrospective analysis of histograms in the form of selectable functions that can be displayed on a viewing screen and to output them together with the converted data combined as picture signals (variability analysis specified by a user who selects specifications from a plurality of pre-defined methods; and continuous display of multiple variability analyses in real time, while permitting user-specified selection of patient parameters, patients and choice of variability analysis, Paragraph [0030]) .

As to claim 11, Seely et al teaches a device, wherein the computer is designed to process control signals that are generated by an input means communicating with the computer and that serve to control the conversion and/or the output of the picture signals (FIG. 1A, the apparatus 100 uses a known individual patient interface and display 106a, having both data input and data output connectors, to provide a display for the variability information).

The limitation of claim 12 and 13 has been addressed above in claim 1.

As to claim 16, Seely et al teaches the medical monitoring device as claimed in claim 13 further comprising an alarm that is triggered when selectable number measurements of histogram data are measured below a selectable threshold level, Alarms can be set so that if a variability histogram is within the normal range, it is displayed in one color (green, for example). If the

value of the histogram rises above or falls below the normal range, it is displayed in a different color (red, for example), paragraph [0089]).

As to claim 17, Seely et al teaches the medical monitoring device as claimed in claim 13, wherein the histogram data is binned into selectably sized histogram bins (The data is plotted in frequency bins, where each bin represents a proportional amount of variation, as measured by the squared difference from the mean, paragraph [0085]).

As to claim 18, Seely et al teaches the medical monitoring device as claimed in claim 13 further comprising display means for displaying real-time signal patterns of the medical measurement data (real-time display, 502, figure 5).

As to claim 19, Seely et al teaches the medical monitoring device as claimed in claim 18, wherein the real-time signal patterns and the histogram data are displayed next to one another (note that the variability analysis may be displayed on a multiple patient display at a central ICU console, as well as individual patient displays, paragraph [0108]) .

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5, 10, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seely et al (US 7,038,595) and in view of Nappholz et al (US 5,792,198).

While Seely et al meets a number of the limitations of the claimed invention, as pointed out more fully above, Seely fails to specifically teach generates a cumulative curve indication of the medical measurement data and outputs it together with the converted data combined as picture signals. Specifically, Nappholz et al. teaches the RRF selector 86 includes an accumulator 92 which monitors the parameter DMV and generates a cumulative histogram which defines several critical values for the cumulative minute volume, wherein the corresponding cumulative MIR values are known from the above table, and therefore the profile 100 is calculated by calculator 94. Preferably the calculator 94 is implemented as a look-up table, (See figure 7 and 8).Because Nappholz et al automatically and dynamically determines the histogram cumulative curve that helps in monitoring indicia about whether the person's fitness level has changed or not and the cumulative curve is displayed concurrently with the histogram data (see figure 5, and paragraph [0083]). It would have been obvious to one of ordinary skill in the art to generate a cumulative curve in Seely analysis process in order to improve visualization of the suspected finding in an earlier period thus assessing the patient condition correctly .Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on 571-272-7453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew W. Johns/
Primary Examiner, Art Unit 2624

Nancy Bitar

3/24/2008